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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,832	07/25/2003	Nick Davis Poynter	620-262	9237

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EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,832	DAVIS POYNTER ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 25-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-24 and 42* is/are rejected.

7)☒ Claim(s) *5,10,13,14 and 42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/25/03,7/8/04,8/2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Office acknowledges the receipt of Applicant's election and sequence listing, filed on 04 May 2006 and 24 August 2006.

Applicant's election of SEQ ID NO:1 in the response filed on 04 May 2006 is nonresponsive because SEQ ID NO:1 is not a feature in any of the pending claims. During a telephone conversation with Ms. Mary Wilson on 08 August 2006, a provisional election was made with traverse to prosecute the invention of SEQ ID NO:213. Affirmation of this election must be made by applicant in replying to this Office action.

Election/Restriction

Applicant elects Group II, claims 4-24 and 42, with traverse. The traversal is on the grounds that there is no search burden in examining the Group I and II together and that the both Groups have the same class and subclass numbers. Applicant's traversal is unpersuasive for the following reasons:

There are different limitations in each Group that require a separate search. While a search of the prior art for one Group may overlap with that of another group, the searches are not co-extensive and thus would be an undue burden on Office resources even if the Groups were placed in the same class and subclass. The PTO classification is merely an administrative convenience and is not dispositive of relatedness of applications. In the instant case, the method of Group II involves a different genetic marker, from ORF68, than the method of Group I, which uses a genetic marker from ORF30. A heavy search burden exists for searching each group of invention as the art

relating to one group would not provide the structural elements and method steps required for the other groups. Accordingly, the searches of an ORF68 marker in Group I are not coextensive with the search of an ORF30 in Group II and pose a serious search burden.

The instant claims are drawn to multiple oligonucleotides, which are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct due to their unique nucleotide sequence. See M.P.E.P. § 803.02. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. As such, the sequences in the instant claims are not considered to constitute a proper Markush group/genus, and are therefore subject to restriction. Furthermore, a search of more than one of the sequences present in these claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search in terms of computer time needed to perform the search and the subsequent analysis of the search results by the examiner. In view of the foregoing, one sequence is considered to be a reasonable number of sequences for examination.

The restriction among the different products that may be used in the claimed methods is maintained. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-42 are pending. Claims 1-3 and 25-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04 May 2006.

Claims 4-24 and 42 are examined to the extent that they read on the elected sequence, SEQ ID NO: 213.

Information Disclosure Statement

The initialed and dated copies of Applicant's IDS form 1449, filed on 25 July 2003, 08 July 2004, and 02 August 2004, respectively, are attached to the instant Office action.

Specification

Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate. In the instant case, the provisional application 60/398,576 is not stated in the first line of the specification. Appropriate correction is required.

Claim Objections

Claims 5, 10, 13, 14 and 42 are objected to because of the following informalities:

Claim 5 refers to the phrase "open reading frame" by the abbreviation ORF without first identifying the full name.

Both claims 10 and 14 are missing the word "strain" between "EHV-1" and "V592".

Claim 13 is missing a period.

Claim 23 refers to the term "restriction fragment length polymorphism" by the abbreviation RFLP without first identifying the full name.

Claim 42 is objected to for containing non-elected subject matter.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd ¶

The following is a quotation of the second paragraph of 35 U.S.C. §112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-9, 17-24, and 42 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-9, 17-24 recite ORF30 without identifying the strain name of the virus. Due to the genetic heterogeneity among the herpesviruses or isolates, there are many species with different nucleotide and amino acid sequences. A skilled artisan would not know whether one designated open reading frame (ORF) in one strain has the same position numbers as the same designated ORF in another strain. Therefore, position

numbers or ORF number in the absence of a reference strain name is vague and indefinite.

Claim 42 contains "use claim" language. Although claim 42 sets forth active method steps, it is unclear whether claim 42 is drawn to the method or the product. Claim 42 has been considered as a method claim for examination purposes. Please amend the claim accordingly.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 112, 1st ¶, Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-24 and 42 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for detecting high virulence of an EHV-1 isolate using a genetic marker corresponding to ORF30 amino acid D752 and/or G760, or nucleotide 2254G and/or 2279G, does not reasonably provide enablement for assessing the virulence with any other genetic marker corresponding to other amino acids or nucleotides in any other viral isolate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors

(MPEP §2164.01(a)). See, *In re Wands*, 8 USPQ2d 1400, at 1404 (CAFC 1988); and *Ex Parte Forman*, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered.

The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

The nature of the invention is a method for assessing the virulence of a herpesvirus, an EHV-1 or EHV-4 isolate, using a genetic marker. The breadth of the claimed invention is exceedingly large and fails to receive adequate support in the specification. Claims 6-24 and 42 encompass the virulence assessment of any herpesvirus, including all sub-families of human herpesviruses, bovine herpesviruses, alcelaphine herpesvirus, equine herpesviruses. The claims are not limited to a single nucleic acid sequence, encompassing the use of a wide variety of gene sequences as virulence markers. The disclosure fails to provide any working embodiments that meet the claimed limitations. While there is two nucleotides, G2254 and G2279, encoding for amino acids Asp752 and Gly760, from EHV-1 strain V592, corresponding to virulence determinants when aligned with the EHV-1 strain AB4. There are no comparisons of the V592 strain sequence with other herpesvirus families or strains. The disclosure is

silent pertaining to any other amino acid residues or nucleotides as virulence markers for herpesviruses. The applicability of the V592 strain marker towards other strains or herpesviruses is highly unpredictable due to the genetic heterogeneity of herpesviruses, as evidenced by the homology and phylogeny analyses published by Ehlers *et al.* (1999). Therefore, without sufficient guidance pertaining to all herpesvirus virulence genetic markers, the skilled artisan has only been extended an undue invitation to further unpredictable experimentation to identify all virulence markers that are common to all herpesviruses.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 4 is rejected under 35 U.S.C. §102(b) as being anticipated by Osterrieder *et al.* (1996).

The instant claim is directed to a method for assessing the virulence of EHV-1 or EHV-4 isolate comprising use of a genetic marker.

Osterrieder *et al.* teach a method of determining virulence of EHV-1 using the IR6 gene from ORF 67 (page 243). Thus, the instant invention is anticipated by Osterrieder *et al.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-7, 9, 17-22 and 24 are rejected under 35 U.S.C. §103(a) as being unpatentable over Osterrieder *et al.* (1996) in view of Ehlers *et al.* (1999).

The instant claims are drawn to a method for assessing the neurovirulence of a herpesvirus isolate comprising use of a DNA polymerase marker from ORF30.

Osterrieder *et al.* teach a method of determining virulence of EHV-1 using the IR6 gene from ORF 67. Equine herpesvirus 1 (EHV-1) is a major pathogen of horses and causes late-time abortions and respiratory and neurological diseases (page 243). The EHV-1 viruses are grown in host cells and purified for Southern blotting (page 244).

Osterrieder *et al.* do not disclose a DNA polymerase marker from ORF30.

Ehlers *et al.* disclose a PCR method, based on primers targeting highly conserved regions of the DNA polymerase genes of known and potentially novel herpesviruses (Abstract). A sample of DNA is provided from the herpesvirus isolate cultivated in host cells that are lysed and extracted (page 212). The consensus PCR primers, an HSV-1-specific primer and a columbid herpes virus 1 specific primer, can function as the claimed DNA polymerase marker to amplify the DNA polymerase genes. The PCR products are sequenced directly. The polymerase variant is confirmed by nucleotide sequencing and sequence alignments (page 214, left column).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Osterrieder *et al.* so as to include the PCR with polymerase consensus primers as taught by Ehlers *et al.* The skilled artisan would have been motivated to do so to amplify the amount of sample DNA and to improve the accuracy of the sequencing result and the virulence assessment. There would have been a reasonable expectation of success, given that the DNA polymerase is used for the replication of the viruses and hence is a virulence factor. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Remarks

No claim is allowable.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP §714.02 and §2163.06.

Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Jeffrey Parkin, Ph.D.
Primary Examiner
2 July 2007

Louise Humphrey, Ph.D.
Assistant Examiner